January 17, 2020</br></br> We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Ian Broverman.

 *** This is a system-generated email notification ***

K193547

Finceramica

December 19, 2019

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: ***Special 510(k) Premarket Notification for the implementation of an additional method of sterilization to the device CustomizedBone Service (K180513).***

Dear Sir/Madam:

Enclosed is the Special 510(k) Premarket Notification ***implementation of an additional method of sterilization to the device CustomizedBone Service (K180513).***

This submission is in the form of one eCopy (USB enclosed) prepared per the Guidance Document entitled "eCopy Program for Medical Device Submissions".

This premarket notification is submitted by Fin-Ceramica Faenza S.p.A., to allow FDA to evaluate the change which is related to the introduction of steam sterilization as an alternative method for sterilization of the CustomizedBone Service.

The FDA's screening checklist for 510(k) special administrative adequacy, *Acceptance Checklist for Special 510(k)s*, is replicated at "Annex 0-1 Acceptance Checklist". General information for this premarket notification is summarized below:

Applicant/Manufacturer [510(k) holder]:

FIN-CERAMICA FAENZA SPA
Via Ravegnana 186
Faenza, RA, 48018 ITALY
Facility Registration Number: 3006130229

1 / 3

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legal seat
via Granarolo 177/3 - 48018 Faenza RA, Italy
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info@finceramica.it - www.finceramica.it
VAT CODE IT 00284400399 - REA RA 115338
share capital € 1.000.000,00

head office
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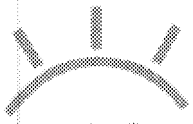
www
public limited company subsidiary
of Tamplast financial group spa



Contact: Marina Monticelli
Telephone: +39 0546 607354
FAX: +39 0546 607337
Email: mmonticelli@finceramica.it

Consultant/Contact:

RCRI®, Regulatory & Clinical Research Institute, Inc.
5353 Wayzata Blvd. Suite 505
Minneapolis, MN 55416

Primary Contact: **Mary Beth Henderson, Ph.D., MBA**
Telephone: Direct: 952-595-5580
Office: 952-746-8080
Mobile: (b)(6)
Fax: 952-884-6518
E-Mail: mbhenderson@rcri.org

Device Name and Classification

Proprietary Name:	CustomizedBone Service
Common Name:	Plate, Cranioplasty, preformed, non-alterable
Classification Name:	Preformed non-alterable cranioplasty plate
Classification Regulation:	21 CFR 882.5330
Product code:	GXN, PJN
Medical Specialty:	Neurology

The information provided in the Table below is provided in accordance with Table 3 of "*Guidance for Industry and FDA Staff – Format for Traditional and Abbreviated 510(k)s.*"

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biological source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
- If yes, does this device type require reprocessed validation data?	NA	NA
Does the device contain a drug?		X

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---
public limited company subsidiary
of Fanplast financial group spa

Finceramica

Question	Yes	No
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission contain clinical information?		X
Is the device implanted?	X	

In accordance with the Safe Medical Devices Act of 1990 and 21 CFR 807.92, a 510(k) Statement is included in SECTION 5 of this premarket notification. A CDRH Premarket Review Submission Cover Sheet (see SECTION 2), Indications for Use Statement (see SECTION 4), and Truthful and Accurate Statement (see SECTION 6) are also included. As required by the Medical Device User Fee and Modernization Act of 2002, the required Medical Device User Fee in the amount of (b)(4) has been submitted separately; a copy of the Medical Device User Fee Cover Sheet is provided in SECTION 1 of this premarket notification.

This special 510(k) premarket notification includes trade secrets and commercial information that are privileged or confidential and, in accordance with 21 CFR 807.95, are not available for public disclosure.

RCRI®, Regulatory & Clinical Research Institute, Inc., is a regulatory consultant for Fin-Ceramica Faenza. If you have any questions regarding this notification, or require additional information, please contact Mary Beth Henderson (952-595-5580 mbhenderson@rcri-inc.com), or alternately Marina Monticelli (+39 0546 607354; mmonticelli@finceramica.it).

Sincerely,

(b)(6)

Marina Monticelli
Regulatory Affairs Specialist
Fin-Ceramica Faenza S.p.A.

3/ 3

Fin-ceramica faenza s.p.a.
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www
public limited company subsidiary
of Tampieri financial group spa

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Hi Hyung,

FinCeramica sent a 4-page response. Please let me know what you think.

-Ian

From: Henderson, Mary Beth <MaryBeth.Henderson@covance.com>
Sent: Wednesday, January 15, 2020 12:12 PM
To: Broverman, Ian <Ian.Broverman@fda.hhs.gov>
Cc: Marina Monticelli <mmonticelli@finceramica.it>
Subject: RE: K193547

Ian—
Please see attached FinCeramica's response to your questions below. Please don't hesitate to e-mail or call, if you have any additional questions.
Best—
Mary Beth

Mary Beth Henderson, Ph.D., MBA
Executive Director, Covance Medical Device and Diagnostic Solutions
Covance Inc
5353 Wayzata Blvd. Suite 505
Minneapolis, MN 55416
Direct: +1-952-595-5580 Main: +1-952-746-8080 Cell: (b)(6)
marybeth.henderson@covance.com

cid:image002.jpg@01

Please note my email address has changed. As of 01 January 2020, RCRI is part of Covance, Medical Device and Diagnostic Solutions. Emails sent to my RCRI email address after January 1st will automatically be forwarded to my Covance email. However, emails from me will be sent from my Covance email address.

From: Broverman, Ian <Ian.Broverman@fda.hhs.gov>
Sent: Tuesday, January 14, 2020 12:00 PM
To: Mary Beth Henderson <mbhenderson@rcri-inc.com>
Subject: [External] K193547
Importance: High

EXTERNAL: This email originated from outside of the organization. Do not click any links or open any attachments unless you trust the sender and know the content is safe.

K193547

Hi Mary Beth,

Below are two requests for additional information from our r (b)(4) If you can respond to them by tomorrow morning, we will do our best to complete the review by Friday.
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(b)(4)

Thank you,

-Ian
Ian Broverman
Medical Device Reviewer

Neurosurgical Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurology and Physical Medicine Devices

Center for Devices and Radiological Health
Office of Product Evaluation and Quality
U.S. Food and Drug Administration
Tel: 301-796-9696
ian.broverman@fda.hhs.gov


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https://www.research.net/s/cdrhcustomerservice?ID=1711&S=E

Hi Mary Beth,

(b)(4)

Thank you,

-Ian

From: Lee, Hyung <Hyung-Yul.Lee@fda.hhs.gov>

Sent: Wednesday, January 15, 2020 2:53 PM

To: Broverman, Ian <Ian.Broverman@fda.hhs.gov>

Subject: RE: K193547

Hi Ian,

Here is the following request I have for the sponsor's response to the interactive review request #1. Please let me know if you have any questions. Thank you.

Hyung

(b)(4)

From: Broverman, Ian <Ian.Broverman@fda.hhs.gov<mailto:Ian.Broverman@fda.hhs.gov>>

Sent: Wednesday, January 15, 2020 1:25 PM

To: Lee, Hyung <Hyung-Yul.Lee@fda.hhs.gov<mailto:Hyung-Yul.Lee@fda.hhs.gov>>

Subject: FW: K193547

Importance: High

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-Ian

From: Henderson, Mary Beth
<MaryBeth.Henderson@covance.com<mailto:MaryBeth.Henderson@covance.com>>

Sent: Wednesday, January 15, 2020 12:12 PM

To: Broverman, Ian <Ian.Broverman@fda.hhs.gov<mailto:Ian.Broverman@fda.hhs.gov>>

Cc: Marina Monticelli <mmonticelli@finceramica.it<mailto:mmonticelli@finceramica.it>>

Subject: RE: K193547

Ian-

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Best-

Mary Beth

Mary Beth Henderson, Ph.D., MBA

Executive Director, Covance Medical Device and Diagnostic Solutions

Covance Inc

5353 Wayzata Blvd. Suite 505

Minneapolis, MN 55416

Direct: +1-952-595-5580 Main: +1-952-746-8080 Cell: (b)(6)

marybeth.henderson@covance.com<mailto:marybeth.henderson@covance.com>

[cid:image002.jpg@01D5C21D.483E24D0]

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From: Broverman, Ian <Ian.Broverman@fda.hhs.gov<mailto:Ian.Broverman@fda.hhs.gov>>

Sent: Tuesday, January 14, 2020 12:00 PM

To: Mary Beth Henderson <mbhenderson@rcri-inc.com<mailto:mbhenderson@rcri-inc.com>>

Subject: [External] K193547

Importance: High

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K193547

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(b)(4)

Thank you,

-Ian

Ian Broverman

Medical Device Reviewer

Neurosurgical Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices

OHT5: Office of Neurology and Physical Medicine Devices

Center for Devices and Radiological Health

Office of Product Evaluation and Quality

U.S. Food and Drug Administration

Tel: 301-796-9696

ian.broverman@fda.hhs.gov<mailto:ian.broverman@fda.hhs.gov>

[cid:image002.png@01D50106.C9360590]<https://nam04.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.proofpoint.com%2Fv2%2Furl%3Fu%3Dhttp-3A__www.fda.gov_%26d%3DDwMFAw%26c%3DS45CfGgG2DnJufDl2zQlS5Cx3WZzz2VHifJShPcdcR4%26r%3DIDoLc0Ru9EvUlU8QwnZqle24OtoSpQFSNbJnTJIl8is%26m%3DgJ5GYuNAW60LlqJJYRvgT60Ipv9VoON0cwIebgtymZ8%26s%3D2vg3icEwWBZlXoJXzQQ6rlmq6cwbKxTRlU6825OSxXI%26e%3D&data=01%7C01%7CMaryBeth.Henderson%40covance.com%7C2bb8e74f5fc44a6e6c4608d7991b864c%7C7b3bf3a5ce934afbabec7bf49544d250%7C1&sdata=y3T0wSd9PUpNLMxkmaFda5GngWFbmmemzaU52%2BFCPuk%3D&reserved=0>

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January 3, 2020</br></br>

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K193547, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Ian Broverman.

 *** This is a system-generated email notification ***

CUSTOMIZEDBONE SERVICE

PATIENT SPECIFIC CRANIAL/CRANIOFACIAL IMPLANT

INSTRUCTIONS for USE

(b)(4)

(b)(4)

(b)(4)

(b)(4)

U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/ODE/DNPMD/NDNB
WO66 RM4202
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-9696

Premarket Notification 510(k) Review

Date: January 16, 2020

Reviewer: Ian Broverman

Subject: Special 510(k)# K193547

Applicant: Fin-Ceramica Faenza Spa	**Device Trade Name:** CustomizedBone Service
Contact Name: Mary Henderson	**Contact Title:** VP Regulatory Affairs and Quality System, System, Senior Principal Advisor
Correspondent Firm: Regulatory and Clinical Research Institute, Inc.	**Phone:** (952) 595-5580 **Email:** mbhenderson@rcri-inc.com
Received Date: December 20, 2019	**Due Date:** January 19, 2020
Pro Code(s): GXN **Class:** II **Reg #:** 882.5330	**Reg Name:** Preformed Nonalterable Cranioplasty Plate
Pro Code(s): PJN Class: II Reg #: 882.5330	Reg Name: Preformed nonalterable cranioplasty plate

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K180513	GXN, PJN	CustomizedBone Service	Fin-Ceramica Faenza S.p.A

Recommendation

I recommend that the CustomizedBone Service is/are Substantially Equivalent (SESE)

(b)(5)

(b)(5)

(b)(5)

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(b)(5)

Digital Signature Concurrence Table (Doc ID: 04500.13.03)	
This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.	
Reviewer Sign-Off	Ian P. Broverman -S Digitally signed by Ian P. Broverman -S Date: 2020.01.17 16:05:28 -05'00'

K193547

Hi Mary Beth,

Below are two requests for additional information from our (b)(4) If you can respond to them by tomorrow morning, we will do our best to complete the review by Friday.

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(b)(4)

Thank you,

-Ian

Ian Broverman

Medical Device Reviewer

Neurosurgical Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices

OHT5: Office of Neurology and Physical Medicine Devices

Center for Devices and Radiological Health

Office of Product Evaluation and Quality

U.S. Food and Drug Administration

Tel: 301-796-9696

ian.broverman@fda.hhs.gov<mailto:ian.broverman@fda.hhs.gov>

[cid:image002.png@01D50106.C9360590]<http://www.fda.gov/>

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U.S. FOOD & DRUG ADMINISTRATION

January 17, 2020

Fin-Ceramica Faenza Spa
% Mary Beth Henderson, Ph.D., M.B.A.
VP Regulatory Affairs and Quality System, System, Senior Principal Advisor
Regulatory and Clinical Research Institute, Inc.
5353 Wayzata Blvd, Suite 505
Minneapolis, Minnesota 55416

Re: K193547
Trade/Device Name: CustomizedBone Service
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GXN, PJN
Dated: December 19, 2019
Received: December 20, 2019

Dear Mary Beth Henderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Matthew C. Krueger -S

Matthew Krueger, M.S.E.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193547

Device Name
CustomizedBone Service

Indications for Use *(Describe)*
CustomizedBone Service (CustomizedBone) is intended to replace bony voids in the cranial and /or craniofacial skeleton (frontal bone including the brow ridge). This device is indicated for both adult and pediatric use (for children 7 years of age and above).
CustomizedBone implants are suitable for reconstructing cranial and/or craniofacial defects resulting from:
• trauma and vascular pathologies, either associated or non-associated to cranial decompression:
• removal of tumours:
• reabsorption of autologous bone:
• rejection of other prosthetic materials:
• congenital malformations.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

U.S. FOOD & DRUG ADMINISTRATION

January 17, 2020

Fin-Ceramica Faenza Spa
% Mary Beth Henderson, Ph.D., M.B.A.
VP Regulatory Affairs and Quality System, System, Senior Principal Advisor
Regulatory and Clinical Research Institute, Inc.
5353 Wayzata Blvd, Suite 505
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Re: K193547
Trade/Device Name: CustomizedBone Service
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www.fda.gov

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Matthew C. Krueger -S

Matthew Krueger, M.S.E.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Department of Health & Human Services **Food and Drug Administration**

MEMORANDUM
(K193547)

Date: January 16, 2020

To: Ian Broverman
Team Leader
DNPMD/NDNB

From: Hyung Lee, PhD
Sterility Reviewer
DNPMD/NSDP

Hyung-yul Lee -S 2020.01.16 15:06:09 -05'00'

Device Name: CustomizedBone Service

Sponsor: Fin-Ceramica Faenza S,P.A

(b)(5)

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Special 510(k) Notification

For

CustomizedBone Service

(Previously Cleared under K180513)

Submission Date: **19 December 2019**

Sponsor: Fin-ceramica faenza s.p.a.

Table of Contents

1.0 MEDICAL DEVICE USER FEE COVERSHEET

The Medical Device User Fee Coversheet (Form FDA 3601) is provided below.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm	
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) FINCERAMICA FAENZA SPA Via Granarolo, 177/3 rmartinetti@finceramica.it Faenza Italy RA 48018 IT 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2. CONTACT NAME Marina Monticelli 2.1 E-MAIL ADDRESS mmonticelli@finceramica.it 2.2 TELEPHONE NUMBER (include Area code) 39-0546607 354 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm	
Select an application type: [X] Premarket notification(510(k)); except for third party [ ] 513(g) Request for Information [ ] Biologics License Application (BLA) [ ] Premarket Approval Application (PMA) [ ] Modular PMA [ ] Product Development Protocol (PDP) [ ] Premarket Report (PMR) [ ] 30-Day Notice [ ] De Novo Request	3.1 Select a center [X] CDRH [ ] CBER 3.2 Select one of the types below [X] Original Application Supplement Types: [ ] Efficacy (BLA) [ ] Panel Track (PMA, PMR, PDP) [ ] Real-Time (PMA, PMR, PDP) [ ] 180-day (PMA, PMR, PDP)
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) [ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA [X] NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:	
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? [X] YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.) [ ] NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)	
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. [ ] This application is the first PMA submitted by a qualified small business, including any affiliates [ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only [ ] The sole purpose of the application is to support conditions of use for a pediatric population [ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA). [ ] YES [X] NO	
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing	

the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paper Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) 13-Dec-2019

2.0 CDRH PREMARKET REVIEW SUBMISSION COVERSHEET (FORM 3514) / AND CERTIFICATION OF COMPLIANCE WITH REQUIREMENTS OF CLINICALTRIALS.GOV DATA BANK (FORM 3674)

2.1. CDRH Premarket Review Submission Coversheet (Form FDA 3514)

The CDRH Premarket Review Submission Coversheet is provided on the pages that follow.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: June 30, 2020
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
12/19/2019	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☒ Special	☐ Submission Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Fin-ceramica faenza spa	3006130229		
Division Name *(if applicable)*	**Phone Number** *(including area code)*		
	0039 0546607311		
Street Address	**FAX Number** *(including area code)*		
via ravegnana 186	0039 0546607312		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Faenza	RA	48018	Italy
Contact Name			
Marina Monticelli			
Contact Title	**Contact E-mail Address**		
RA Specialist	mmonticelli@fincoramica.it		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Regulatory and Clinical Research Institute , Inc.			
Division Name *(if applicable)*	**Phone Number** *(including area code)*		
	952.595.5580		
Street Address	**FAX Number** *(including area code)*		
5353 Wayzata Blvd. Suite 505	952.894.6518		
City	**State / Province**	**ZIP Code**	**Country**
Minneapolis	MN	55416	U.S.A.
Contact Name			
Mary Beth Henderson			
Contact Title	**Contact E-mail Address**		
VP Regulatory Affairs and Quality System , Senior Principal Advisor	mbhenderson@rcri-inc.com		

FORM FDA 3514 (9/17) Page 1 of 5 Pages

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☒ Other Reason *(specify)*:

  Addition of an alternate method for sterilization (steam).

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GXN	2	PJN	3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☐ 510 (k) summary attached
☒ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K180513	1	CustomizedBone Service	1	Fin-ceramica faenza s.p.a.
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Common name: Plate,Cranioplasty, preformed, non alterable
Classification: Preformed nonalterable cranioplasty plate

	Trade or Proprietary or Model Name for This Device		Model Number
1	CustomizedBone Service	1	NA
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K180513	2 K170515	(b)(4)	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
GXN, PJN	21 CFR 882.5330: Plate, Cranioplasty, preformed, non alterable	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Indications *(from labeling)*

CustomizedBone Service (CustomizedBone) is intended to replace bony voids in the cranial and/or craniofacial skeleton (frontal bone including the brow ridge). This device is indicated for both adult and pediatric use (for children 7 years of age and above).
CustomizedBone implants are suitable for reconstructing cranial and/or craniofacial defects resulting from:
• trauma and vascular pathologies, either associated or non-associated to cranial decompression, • removal of tumors; • reabsorption of autologous bone; • rejection of other prosthetic materials; • congenital malformations

FORM FDA 3514 (9/17) Page 3 of 5 Pages

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Fin-ceramica faenza s.p.a.		Establishment Registration Number: 3006130229	
Division Name *(if applicable)*		Phone Number *(including area code)*: 0039 054 607311	
Street Address: via Ravegnaga 186		FAX Number *(including area code)*: 0039 054 607312	
City: Faenza	State / Province: RA	ZIP Code: 48018	Country: Italy
Contact Name: Marina Monticelli	Contact Title: Regulatory Affairs Specialist	Contact E-mail Address: mmonticelli@finceramica.it	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

FORM FDA 3514 (9/17) Add Continuation Page Page 4 of 5 Pages

SECTION I **UTILIZATION OF STANDARDS**

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	10993-1	ISO	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	Fourth edition	10/15/2009
2	10993-5	ISO	Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity	-	06/01/2009
3	10993-17	ISO	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances	-	12/01/2002
4	10993-18	ISO	Biological evaluation of medical devices - Part 18: Chemical characterization of materials	-	07/01/2005
5	13779-1	ISO	Implants for surgery - Hydroxyapatite - Part 1: Ceramic hydroxyapatite	Second Edition	10/01/2008
6	13779-3	ISO	Implants for surgery - Hydroxyapatite - Part 3: Chemical analysis and characterization of crystallinity and phase purity	Second Edition	02/01/2008
7	11737-2	ISO	Sterilization of medical devices - Microbiological methods Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	-	11/15/2009

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

FORM FDA 3514 (9/17) Page 5 of 5 Pages

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
1	Standards No. 11135-1	Standards Organization ISO	Standards Title Sterilization of health care products–Moist heat–Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	Version First edition	Date 08/15/2006
2	Standards No. 11607-1	Standards Organization ISO	Standards Title Packaging for terminally sterilized medical devices – Part 1: requirements for materials, sterile barrier systems and packaging systems	Version 1st edition	Date 04/15/2009
3	Standards No. F88/F88M-15	Standards Organization ASTM	Standards Title Standard Test Method for Seal Strength of Flexible Barrier Materials	Version -	Date 03/01/2015
4	Standards No. F1929-15	Standards Organization ASTM	Standards Title Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	Version -	Date 01/01/2015
5	Standards No. <5>	Standards Organization USP	Standards Title Bacterial Endotoxins test	Version	Date 01/01/2015
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version -	Date

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

"DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW."

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

FORM FDA 3514 (1/13) Page 5 of 5 Pages

2.2. Certification of Compliance with Requirements of ClinicalTrials.gov Data Bank (Form FDA 3674)

The completed Form FDA 3674 (Certification of Compliance with Requirements of ClinicalTrials.gov Data Bank) is provided on the pages that follow, indicating the requirements do not apply because this submission does not reference any clinical trial.

Form Approved: OMB No. 0910-0616, Expiration Date: 3/31/2021, See PRA Statement below.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter
Fin-ceramica faenza spa

2. Date of the Application/Submission
12/19/2019

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*
via ravegnana 186

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City
faenza

State/Province/Region
RA

Country
Italy

ZIP or Postal Code
48018

4. Telephone and Fax Numbers *(include country code if applicable and area code)*

(Tel): 0039 0546607311

(Fax): 0039 0546607312

PRODUCT INFORMATION

5. For Drugs/Biologics: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

CustomizedBone Service
Product codes: OXN, FTN. 21 CFR 882.5330: Plate, Cranioplasty, preformed, non alterable

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number *(If number previously assigned)*

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, including 42 CFR part 11, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, including 42 CFR part 11, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that the requirements of 42 U.S.C. 282(j), including any applicable provisions of 42 CFR part 11, have been met.

Certification Statement / Information section continued on page 2

CERTIFICATION STATEMENT / INFORMATION *(Continued)*

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," for which you (the sponsor/applicant/submitter) are the "responsible party" under 42 U.S.C. § 282(j)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act referenced in the application/ submission which this Certification accompanies. (Add continuation page as necessary.)

NCT Number(s):

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name	Title
Alessandra Tampieri	President

12. Address

Address 1 *(Street address, P.O. box, company name c/o)*	
c/o Via Granarolo 177/C	
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	
City: Ilanza	State/Province/Region: RA
Country: Italy	ZIP or Postal Code: 48018

13. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): 0039 0546 607311

(Fax): 0039 0546 607312

14. Date of Certification

12/03/2019

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative (Sign)

Sign

(b)(6)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/ submission) per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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3.0 SPECIAL 510(K) COVER LETTER

Finceramica

December 19, 2019

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: ***Special 510(k) Premarket Notification for the implementation of an additional method of sterilization to the device CustomizedBone Service (K180513).***

Dear Sir/Madam:

Enclosed is the Special 510(k) Premarket Notification ***implementation of an additional method of sterilization to the device CustomizedBone Service (K180513).***

This submission is in the form of one eCopy (USB enclosed) prepared per the Guidance Document entitled "eCopy Program for Medical Device Submissions".

This premarket notification is submitted by Fin-Ceramica Faenza S.p.A., to allow FDA to evaluate the change which is related to the introduction of steam sterilization as an alternative method for sterilization of the CustomizedBone Service.

The FDA's screening checklist for 510(k) special administrative adequacy, *Acceptance Checklist for Special 510(k)s*, is replicated at "Annex 0-1 Acceptance Checklist".
General information for this premarket notification is summarized below:

Applicant/Manufacturer [510(k) holder]:

FIN-CERAMICA FAENZA SPA
Via Ravegnana 186
Faenza, RA, 48018 ITALY
Facility Registration Number: 3006130229

Fin-ceramica faenza spa
legal seat
via Granarolo 177/3 - 48018 Faenza RA, Italy
t +39 0546 607311 - f +39 0546 607382 - CP 107
info@finceramica.it - www.finceramica.it
VAT CODE IT 01025400399 - REA RA 155338
share capital € 1.000.000,00

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---
public limited company subsidiary
of Fenplast financial group spa

Finceramica

Contact: Marina Monticelli
Telephone: +39 0546 607354
FAX: +39 0546 607337
Email: mmonticelli@finceramica.it

Consultant/Contact:

RCRI®, Regulatory & Clinical Research Institute, Inc.
5353 Wayzata Blvd. Suite 505
Minneapolis, MN 55416

Primary Contact: **Mary Beth Henderson, Ph.D., MBA**
Telephone: Direct: 952-595-5580
Office: 952-746-8080
Mobile: (b)(6)
Fax: 952-884-6518
E-Mail: mbhenderson@rcri-inc.com

Device Name and Classification

Proprietary Name:	CustomizedBone Service
Common Name:	Plate, Cranioplasty, preformed, non-alterable
Classification Name:	Preformed non-alterable cranioplasty plate
Classification Regulation:	21 CFR 882.5330
Product code:	GXN, PJN
Medical Specialty:	Neurology

The information provided in the Table below is provided in accordance with Table 3 of "*Guidance for Industry and FDA Staff – Format for Traditional and Abbreviated 510(k)s.*"

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biological source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
- If yes, does this device type require reprocessed validation data?	NA	NA
Does the device contain a drug?		X

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www
public limited company subsidiary
of Tamplast financial group spa

Finceramica

Question	Yes	No
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission contain clinical information?		X
Is the device implanted?	X	

In accordance with the Safe Medical Devices Act of 1990 and 21 CFR 807.92, a 510(k) Statement is included in SECTION 5 of this premarket notification. A CDRH Premarket Review Submission Cover Sheet (see SECTION 2), Indications for Use Statement (see SECTION 4), and Truthful and Accurate Statement (see SECTION 6) are also included. As required by the Medical Device User Fee and Modernization Act of 2002, the required Medical Device User Fee in the amount of (b)(4) has been submitted separately; a copy of the Medical Device User Fee Cover Sheet is provided in SECTION 1 of this premarket notification.

This special 510(k) premarket notification includes trade secrets and commercial information that are privileged or confidential and, in accordance with 21 CFR 807.95, are not available for public disclosure.

RCRI®, Regulatory & Clinical Research Institute, Inc., is a regulatory consultant for Fin-Ceramica Faenza. If you have any questions regarding this notification, or require additional information, please contact Mary Beth Henderson (952-595-5580 mbhenderson@rcri-inc.com), or alternately Marina Monticelli (+39 0546 607354; mmonticelli@finceramica.it).

Sincerely,

(b)(6)

Marina Monticelli
Regulatory Affairs Specialist
Fin-Ceramica Faenza S.p.A.

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4.0 INDICATIONS FOR USE STATEMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
CustomizedBone Service

Indications for Use *(Describe)*
CustomizedBone Service (CustomizedBone) is intended to replace bony voids in the cranial and/or craniofacial skeleton (frontal bone including the brow ridge) . This device is indicated for both adult and pediatric use (for children 7 years of age and above).
CustomizedBone implants are suitable for reconstructing cranial and/or craniofacial defects resulting from:
• trauma and vascular pathologies, either associated or non-associated to cranial decompression;
• removal of tumours;
• reabsorption of autologous bone;
• rejection of other prosthetic materials;
• congenital malformations.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5.0 SPECIAL 510(K) STATEMENT

510(K) STATEMENT

(As Required By 21 CFR 807.93)

I certify that, in my capacity as legal representative/managing director of Fin-Ceramica Faenza S.pA, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

(b)(6)

(Signature)

Alessandra Tampieri

(Typed Name)

12/09/2019

(Date)

Not assigned yet

(Premarket Notification [510(k)] Number)

6.0 TRUTHFUL AND ACCURACY STATEMENT

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT.

[As Required by 21CFR 807.87(k)]

I certify that, in my capacity as legal representative of Fin-Ceramica Faenza SpA, , I believe to the best of my knowledge, that all data and information submitted in the premarket notification of CustomizedBone Service are truthful and accurate and that no material fact has been omitted.

(b)(6)

(Signature)

Alessandra Tampieri

(Typed Name)

12/09/2019

(Date)

Not assigned yet

(Premarket Notification [510(k)] Number)

7.0 CLASS III SUMMARY AND CERTIFICATION

A Class III Summary and Certification is not relevant to this Special 510(k) Premarket Notification as this device is Class II.

8.0 FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

A financial certification or disclosure statement is not relevant to this Special 510(k) Premarket Notification as this submission does not contain reports of human clinical studies.

9.0 DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

9.1. Declaration of Conformity

In accordance with 21 C.F.R. §807.87, this section is not required for a Special 510(k) submission. A Declaration of Conformity to FDA recognized consensus standards is not provided.

9.2. Applicable Standards

Fin-ceramica faenza certifies that the CustomizedBone Service devices comply with all applicable requirements in the voluntary standards and FDA recognized consensus standards provided within the test summary sections (Sections 14, 15 and 18) of this submission. Basis of use for a non-recognized consensus standard is provided within the submission testing section summaries and/or within the test protocols and reports.

Verification Activities

To the best of my knowledge, the verification activities, as required by the risk analyses, for the modifications were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

(b)(6)

12/12/2019
Date

Title: QA Manager

Company: Fin-ceramica Faenza spa

Manufacturing Facility

The manufacturing facility of Fin-ceramica Faenza spa , is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

(b)(6)

12/12/2019
Date

Name: Gianluca Fantini

Title: CEO

Company: Fin-ceramica Faenza spa

10.0 EXECUTIVE SUMMARY

CustomizedBone Service was originally cleared for marketing under (b)(4) by Fin-ceramica faenza s.p.a. (the 510(k) holder). Subsequent submissions regarding the CustomizedBone Service include a 510(k) (K171507), for labeling modifications (brochure), and a 510(k) (K180513) for a change to the Indications for Use to include children 7 years of age and above.

CustomizedBone Service is currently sterilized by gamma irradiation.

The purpose of this **Special 510(k) Premarket Notification** is to notify FDA of the intent by Fin-ceramica faenza s.p.a. (Fin-ceramica) to **add steam sterilization** (b)(4) **as an alternative method for sterilization of CustomizedBone Service**.

The indications for use, design, materials, and fundamental scientific technology of the subject device remain the same as the original (predicate) device.

This submission demonstrates substantial equivalence of the subject CustomizedBone Service device (sterilized using steam) to the previously cleared CustomizedBone Service device (K180315; sterilized using gamma irradiation).

(b)(4)

10.1. Description of the Device

CustomizedBone Service replaces bony voids in the cranial/craniofacial skeleton. CustomizedBone Service is indicated for both adult and pediatric use (for children 7 years of age and above). The implants are preformed / pre-shaped to fit the anatomy of the patient, with a (b)(4) and attached to the native bone using standard non-resorbable and (b)(4) (b)(4)

CustomizedBone Service is designed individually for each patient to correct defects in cranial bone. The product, individually sized and shaped implantable prosthetic cranioplasty plates, is intended to fill defects in a specific patient's cranial skeleton. The implants, made of (b)(4) (b)(4) are designed starting from the patient's CT imaging data. These single-use devices are currently provided sterile using a validated gamma-radiation process, and cannot be re-sterilized.

10.2. Indication for Use

CustomizedBone Service (CustomizedBone) is intended to replace bony voids in the cranial and/or craniofacial skeleton (frontal bone including the brow ridge). This device is indicated for both adult

and pediatric use (for children 7 years of age and above).

CustomizedBone implants are suitable for reconstructing cranial and/or craniofacial defects resulting from:

- ✓ trauma and vascular pathologies, either associated or non-associated to cranial decompression;
- ✓ removal of tumours;
- ✓ reabsorption of autologous bone;
- ✓ rejection of other prosthetic materials;
- ✓ congenital malformations.

10.3. Design Control Activities

(b)(4)

The declaration of conformity with design controls is provided in **Section 9.1** of this submission.

10.4. Substantial Equivalence Discussion

The subject device, CustomizedBone Service, manufactured by Fin-ceramica, is identical to the original (predicate) device CustomizedBone Service (K180513) regarding intended use, technology, and principles of operation. As shown Table 10-1 below, the only differences between the subject and the predicate device are in regard to the method of sterilization and the associated primary packaging. The proposed change - **addition of steam sterilization** (b)(4) **as an alternative sterilization method** - to the cleared CustomizedBone Service (K180513) does not affect safety, effectiveness, indications for use, design, materials, or fundamental scientific technology of the device.

Device Characteristics	CustomizedBone Service (Subject Device)	CustomizedBone Service (Predicate Device) K180513	Comment
Manufacturer	Fin-ceramica faenza s.p.a.	Fin-ceramica faenza s.p.a.	Same
Classification regulation	21 CFR § 882.5330	21 CFR § 882.5330	Same
Classification Name (Product Code)	Preformed Non–alterable Cranioplasty Plate (GXN, PJN)	Preformed Non–alterable Cranioplasty Plate (GXN, PJN)	Same
Device description	Individually sized and shaped implantable prosthetic cranioplasty plates.	Individually sized and shaped implantable prosthetic cranioplasty plates.	Same
Intended use	To replace bony voids in the cranial/craniofacial skeleton.	To replace bony voids in the cranial/craniofacial skeleton.	Same
Indication for use	Adult and pediatric use (for children 7 years of age and above).	Adult and pediatric use (for children 7 years of age and above).	Same
Materials Bioabsorbable Design and technical specifications Size	(b)(4)		
Sterilization	Provided Sterile Sterilization Method(s): • Gamma irradiation • Steam	Provided Sterile Sterilization Method(s): • Gamma irradiation	Substantially Equivalent
Packaging	Gamma sterilized: (b)(4) (b)(4) Steam sterilized: (b)(4) (b)(4)	Gamma sterilized: (b)(4) (b)(4)	Substantially Equivalent
Surgical technique	Standard practice	Standard practice	Same
Fixation method	(b)(4)		

Table 10-1 Comparison Table for Determination of Substantial Equivalence

10.5. Conclusion

The proposed change - **addition of steam sterilization as an alternative sterilization method** - does not affect the safety or the effectiveness of the CustomizedBone Service. The indications for use, design, materials, and fundamental scientific technology of the subject device remain the same as the original (predicate) device.

The subject device remains substantially equivalent to the original (predicate) device.

11.0 DEVICE DESCRIPTION

11.1 Device Name and Classification

Common or Usual Name:	Patient Specific Cranial Implant
Proprietary Name:	CustomizedBone Service
Classification Name:	Preformed non-alterable cranioplasty plate
	21 CFR §882.5330
Classification Panel:	Neurology
Product Codes:	GXN, PJN
Class:	II

11.2 Device Description

CustomizedBone Service[1] devices are customized implants for cranial and craniofacial defect reconstruction and are made (b)(4)

(b)(4)

(b)(4)

(b)(4)

Figure 11-1. (b)(4) Structure of CustomizedBone Service

(b)(4)

Figure 11-2. CustomizedBone Service 3D synchrotron radiation microtomography (micro-CT)

The implants are designed and produced by Fin-ceramica according to the prescribing surgeon's specifications and patient specific CT scan data.

The product satisfies the requirements of ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, and the FDA guidance, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (issued in 2016) as previously submitted to FDA for the predicate device (b)(4) and as supported by the additional biocompatibility testing presented within Section 15 of this submission.

All CustomizedBone Service products are supplied sterile. The products are single-use and cannot be re-sterilized.

11.3 Indications for Use

CustomizedBone Service (CustomizedBone) is intended to replace bony voids in the cranial and/or craniofacial skeleton (frontal bone including the brow ridge). This device is indicated for both adult and pediatric use (for children 7 years of age and above).

CustomizedBone implants are suitable for reconstructing cranial and/or craniofacial defects resulting from:

- ✓ trauma and vascular pathologies, either associated or non-associated to cranial decompression;
- ✓ removal of tumours;
- ✓ reabsorption of autologous bone;
- ✓ rejection of other prosthetic materials;
- ✓ congenital malformations.

11.4 Material of Construction

(b)(4)

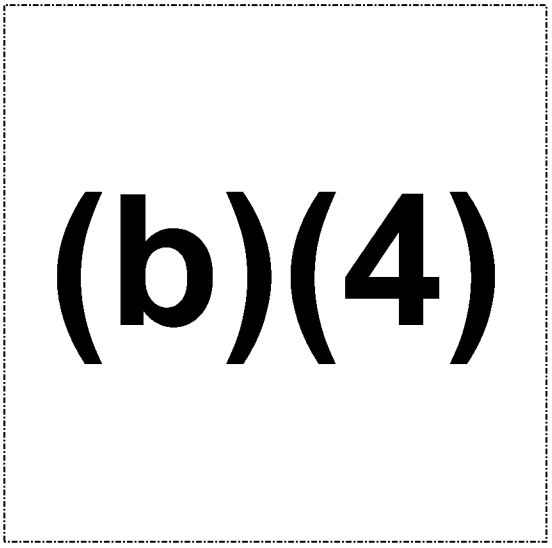


Figure 11-3. CustomizedBone Service (b)(4) structure (b)(4)

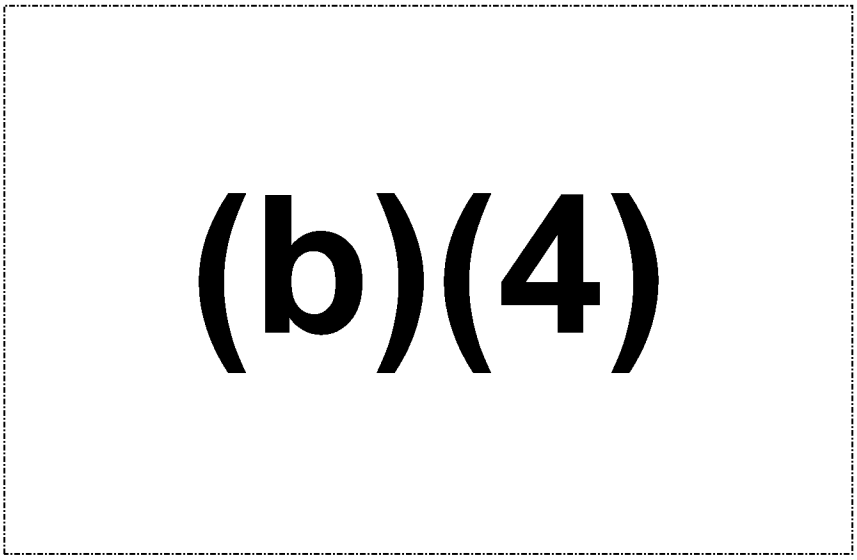


Figure 11-4. CustomizedBone Service (b)(4) structure (b)(4)

11.5 Performance Characteristics

HA is a calcium phosphate which is used frequently in reconstructive surgery because its structure and chemical composition is very similar to that of the mineral phase of bone. The CustomizedBone Service HA has been developed to have porosity properties very similar to those of natural bone, while maintaining sufficient rigidity and mechanical resistance to allow Fin-ceramica to produce a solid, pre-molded implant suitable for housing cells responsible for bone regeneration.

CustomizedBone Service devices are manufactured (b)(4)
(b)(4)

(b)(4)

11.6 Photos and Drawings

The figure below provides representative images related to the CustomizedBone Service device:

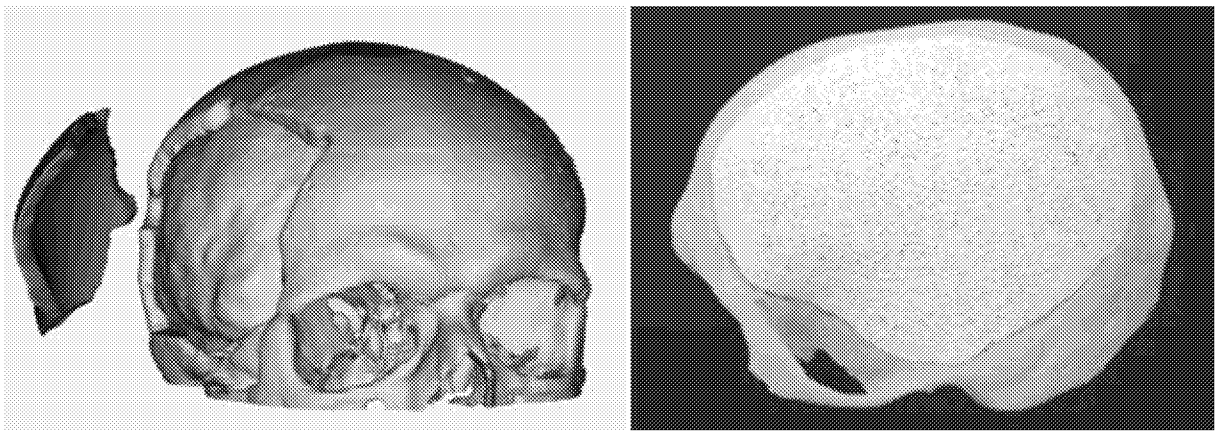


Figure 11-5. Representation of the device function

12.0 SUBSTANTIAL EQUIVALENCE DISCUSSION

12.1. Introduction

- Subject Device:

  Common name: CustomizedBone Service
  Classification name: Preformed Non–alterable Cranioplasty Plate
  Product Code: GXN, PJN

- Predicate Device (legally marketed):

  Common name: CustomizedBone Service
  510k number: K180513
  Classification name: Preformed Non–alterable Cranioplasty Plate
  Product Code: GXN, PJN

This special 510(k) demonstrates the substantial equivalence of the subject device, CustomizedBone Service (sterilized using steam), to the previously cleared original (predicate) device, CustomizedBone Service (K180315; sterilized using gamma irradiation).

The indications for use, design, materials, and fundamental scientific technology of the subject device remain the same as the predicate device.

A comparison of the proposed and the predicate devices is presented in the table below.

Device Characteristics	CustomizedBone Service (Subject Device)	CustomizedBone Service (Predicate Device) K180513	Comment
Manufacturer	Fin-ceramica faenza s.p.a.	Fin-ceramica faenza s.p.a.	Same
Classification regulation	21 CFR § 882.5330	21 CFR § 882.5330	Same
Classification Name (Product Code)	Preformed Non–alterable Cranioplasty Plate (GXN, PJN)	Preformed Non–alterable Cranioplasty Plate (GXN, PJN)	Same
Device description	Individually sized and shaped implantable prosthetic cranioplasty plates.	Individually sized and shaped implantable prosthetic cranioplasty plates.	Same
Intended use	To replace bony voids in the cranial/craniofacial skeleton.	To replace bony voids in the cranial/craniofacial skeleton.	Same

Device Characteristics	CustomizedBone Service (Subject Device)	CustomizedBone Service (Predicate Device) K180513	Comment
Indication for use	Adult and pediatric use (for children 7 years of age and above).	Adult and pediatric use (for children 7 years of age and above).	Same
Materials Bioabsorbable Design and technical specifications Size	(b)(4)		
Sterilization	Provided Sterile Sterilization Method(s): • Gamma irradiation • Steam	Provided Sterile Sterilization Method(s): • Gamma irradiation	(b)(4)
Primary Packaging	Gamma sterilized: (b)(4) Steam sterilized: (b)(4)	Gamma sterilized: (b)(4)	
Surgical technique	Standard practice	Standard practice	
Fixation method	(b)(4)		

Table 12-1 Substantial Equivalence Comparison Table

12.2. Device Description Comparison

The device description of the subject device and the predicate device are the same.

12.3. Intended Use Comparison

The intended use of the subject device and the predicate device are the same.

12.4. Indication for Use Comparison

The indication for use of the subject device and the predicate device are the same.

12.5. Technical and Functional Comparison

- Material: The subject device and the predicate device are made of the same material.

- (b)(4)
- Design and technical specifications: This change does not affect design and technical specifications; therefore, the subject and predicate devices are equivalent.
- Size: Based on the size of the implants, the subject and the predicate devices are equivalent.
- Mechanical performance test in physiological condition: The proposed change does not affect mechanical performance of the device as showed in section 17. For this reason, the subject and predicate devices are substantially equivalent.
- Sterilization: Both predicate and subject device are supplied sterile for single use and cannot be re-sterilized. The predicate is sterilized only by gamma irradiation, whereas the subject device may also be sterilized with the alternative steam sterilization method.

  Although a new method of sterilization has been introduced as an alternative method, the sterilization has been validated and does not raise any questions of safety or effectiveness.
- Packaging: The primary packaging of the gamma irradiated product will continue to consist of (b)(4)

  (b)(4)

  The primary packaging of product intended for steam sterilization will consist of (b)(4)

  (b)(4)

  (b)(4) The new packaging has been validated and does not raise any questions of safety or effectiveness.
- Surgical technique: The subject device and the predicate device are implanted using standard neurosurgical practice.
- Fixation method: Fixation methods for predicate and subject device are equivalent.

12.6. Conclusions

As shown above, the only change proposed to the predicate cleared CustomizedBone Service device (K180513) is to add steam sterilization as an alternative sterilization method.

The indications for use, design, materials, and fundamental scientific technology of the subject device remain the same as the original (predicate) device.

As shown in sections 14 (Sterilization and Shelf Life), 15 (Biocompatibility) and 18 (Performance Testing – Bench), this change does not affect safety or the effectiveness of the CustomizedBone

Service device and the subject and predicate devices can therefore be considered substantially equivalent.

13.0 PROPOSED LABELING

13.1. Instructions for use (IFU)

Minor updates to the IFU will be implemented as a result of this change. These changes include:

(b)(4)

A redlined copy of the draft proposed labeling clearly showing the above changes is provided as **Annex 13-1**.

A clean copy of the draft proposed labeling incorporating the above changes is provided as **Annex 13-2**.

13.2. Packaging Handling Instructions

A copy of the proposed packaging handling instructions for the steam sterilized product is provided as **Annex 13-3**.

13.3. Primary and Secondary Package Labels

The only change for the proposed primary and secondary package labels, as shown below, is the sterilization method symbol (which is defined in the Symbols Glossary table presented in the CustomizedBone IFU).

No changes are being made to the primary and secondary package labels for the product sterilized by gamma irradiation.

No changes are being made to the outer sales box.

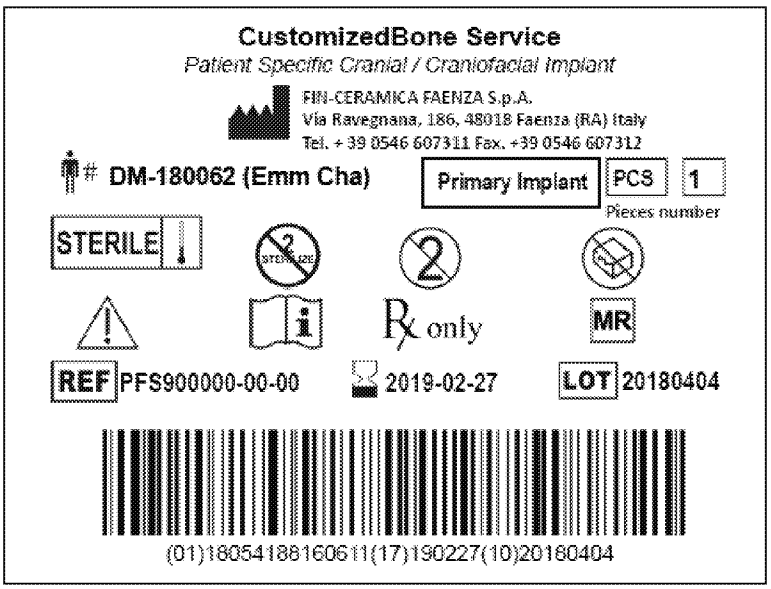
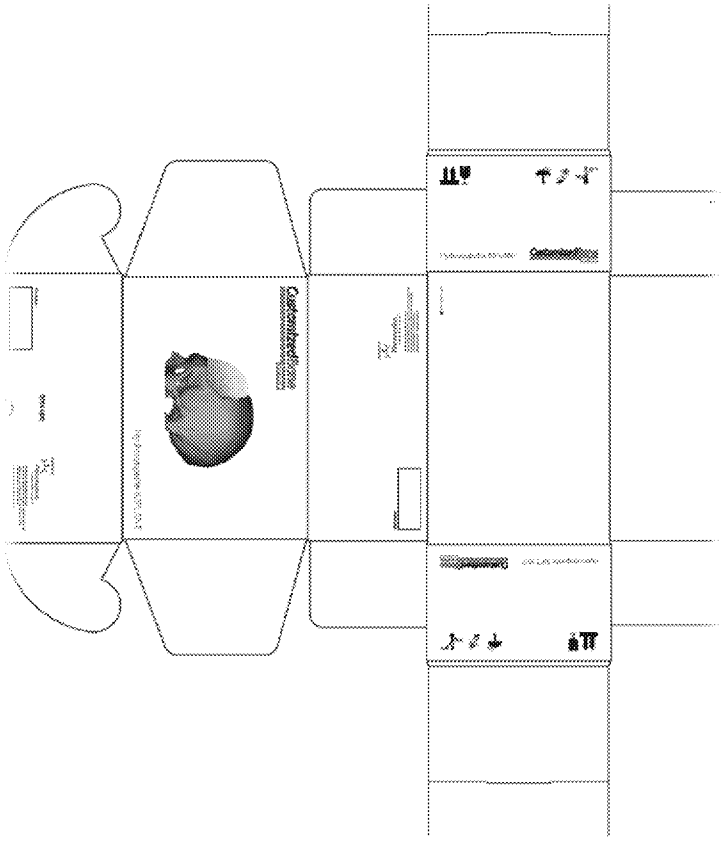


Figure 13-1. Example Label for the primary and secondary package



(For reference only - no changes are being implemented as a result of this change)

Figure 13-2. Sales Box

14.0 STERILIZATION AND SHELF LIFE

14.1. Sterilization Validation

The CustomizedBone Service devices are supplied STERILE for single use and cannot be re-sterilized. The devices are currently sterilized using gamma irradiation to a SAL of 10^{-6}.

The purpose of this submission is to include an alternative steam sterilization method (b)(4) (b)(4) in addition to the gamma irradiation sterilization method currently in place for CustomizedBone Service; no changes are being introduced regarding the current gamma irradiation method.

(b)(4)

Methods:

The proposed alternative steam sterilization method was validated as described in the validation protocol and in accordance with the following standards:

- ISO 17665-1 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 11737-2 Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

The results demonstrate that the product and the packaging were not affected by the new sterilization method.

14.2. Packaging and Shelf-life

The primary packaging of the gamma irradiated product will continue to consist of (b)(4) g

(b)(4)

The primary packaging of product intended for steam sterilization will consist of (b)(4)

(b)(4)

The new packaging has been validated and does not raise any questions of safety or effectiveness.

14.2.1. Real-time Stability

A real-time stability test was carried out on the steam sterilized product. Packaging and product stability were tested over time , specifically at (b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

14.2.2. Transit Simulation test

(b)(4)

(b)(4)

(b)(4)

(b)(4)

15.0 BIOCOMPATIBILITY

CustomizedBone Service has been identified as a permanent implantable device with tissue/bone contact (> 30 days). The suggested biocompatibility testing according to ISO-10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process, and the FDA guidance, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (issued in 2016) incudes: cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (subacute toxicity), genotoxicity, and implantation biocompatibility testing. This series of testing was previously conducted using representative devices under Good Laboratory Practice (GLP) as provided and assessed in the original CustomizedBone Service Traditional 510(k) cleared under (b)(4)

With the decision to introduce steam sterilization as an alternative method for the CustomizedBone Service, the product sterilized by steam was subsequently tested for cytotoxicity in alignment with the decision process flow within ISO 10993-1. In addition, a chemical characterization of the product was performed (in alignment with ISO 10993-18) to assess the biocompatibility of the steam sterilized CustomizedBone Service (subject device) and compare it to the predicate device sterilized by gamma irradiation.

Rationale for the product selected for Biocompatibility test

(b)(4)

(b)(4)

15.1. Cytotoxicity Testing

(b)(4)

(b)(4)

15.2. Chemical Characterization Testing

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

16.0 SOFTWARE

This section does not apply.

17.0 ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

This section does not apply.

18.0 PERFORMANCE TESTING - BENCH

CustomizedBone Service is composed of (b)(4) The chemical (b)(4) As the proposed device is intended for use as a surgical implant, the requirements of ISO 13779-1 Implants for surgery -- Hydroxyapatite -- Part 1: Ceramic hydroxyapatite[1], have been verified.

(b)(4)

18.1. Chemical Analysis

Reference standard: ISO 13779-3: 2008

Reference document: Technical Report - Contract for services of chemical and chemical-physical characterization between (b)(4) and FINCERAMICA FAENZA SpA (b)(4)

Summary of results: (b)(4)

(b)(4)

(b)(4)

(b)(4)

Table 18-1. Chemical analysis results

The results are in compliance with the specification and confirm the substantial equivalence of the product sterilized by steam with the cleared product sterilized by gamma rays (K180513).

18.2. Crystalline Phase Compositions

Reference standard: ISO 13779-3: 2008

Reference document: Technical Report - Contract for services of chemical and chemical-physical characterization between (b)(4) and FINCERAMICA FAENZA SpA (b)(4)

Summary of results: (b)(4)

(b)(4)

(b)(4)

Table 18-2. Crystalline phase compositions results

The results are in compliance with the specification and confirm the substantial equivalence of the product sterilized by steam with the cleared product sterilized by gamma rays (K180513).

18.3. Crystallinity Value

Reference standard: ISO 13779-3: 2008

Reference document: Technical Report - Contract for services of chemical and chemical-physical characterization between (b)(4) and FINCERAMICA FAENZA SpA (b)(4)

Summary of results: (b)(4)

(b)(4)

(b)(4)

(b)(4)

Table 18-3. Crystallinity Value results

The results are in compliance with the specification and confirm the substantial equivalence of the product sterilized by steam with the cleared product sterilized by gamma rays (K180513).

18.4. Trace Elements

Reference standard: ISO 13779-1

Reference document: Certificate of Analysis (b)(4)

Summary of results: (b)(4)

(b)(4)

(b)(4)

Table 18-4. Trace elements results

(b)(4)

Moreover, the device was tested according to ISO 10993-1 and all the results confirm the fact that the device is completely biocompatible and non-toxic.

18.5. Mechanical Properties – Compression Test

Reference standard: ISO 13779-1: 2008

Reference document: Steam sterilization process on CustomizedBone Service Validation report (b)(4).

Summary of results: (b)(4)

(b)(4)

The test results are summarized in the following table:

Table 18-5. Mechanical properties – compression test results

(b)(4)

Table 18-6. Mechanical properties – compression test results

The results are in compliance with the specification and confirm the substantial equivalence of the product sterilized by steam with the cleared product sterilized by gamma rays (K180513).

19.0 PERFORMANCE TESTING - ANIMAL

This section is not applicable as no animal testing was required or conducted. There are no changes between the subject device and the predicate device (K180513) related to this section of the submission.

20.0 PERFORMANCE TESTING - CLINICAL

This section is not applicable as no clinical testing was required. There are no changes between the subject device and the predicate device (K180513) related to this section of the submission.

21.0 LIST OF ANNEXES

Please note: Annexes are numbered in relation to their related section within this submission.

Annex	Document Title / Description	Document Number
0-1	Acceptance Checklist	-
13-1	Draft Proposed IFU – CustomizedBone Service – Redline	(b)(4)
13-2	Draft Proposed IFU – CustomizedBone Service – Clean	
13-3	Proposed packaging handling instructions – CustomizedBone Service	

Dear Ms. Henderson,

Happy new year. I am leading the review of K193547, and look forward to working with you. To expedite the process, I have a couple of requests:

Please email me a clean copy of the Indications for Use form 3881, without the headers & footers from the submission. You may add the 510(k) number K193547 to the form, or I can add it when we complete the file.

(b)(4)

Thank you very much,

-Ian

Ian Broverman

Medical Device Reviewer

Neurosurgical Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices

OHT5: Office of Neurology and Physical Medicine Devices

Center for Devices and Radiological Health

Office of Product Evaluation and Quality

U.S. Food and Drug Administration

Tel: 301-796-9696

ian.broverman@fda.hhs.gov<mailto:ian.broverman@fda.hhs.gov>

[cid:image002.png@01D50106.C9360590]<http://www.fda.gov/>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1711&S=E

From: Ian Broverman <ian.broverman@fda.hhs.gov>

Sent: Friday, January 3, 2020 11:34 AM

To: mbhenderson@rcri-inc.com

Cc: Broverman, Ian <Ian.Broverman@fda.hhs.gov>

Subject: K193547 was Accepted

January 3, 2020

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K193547, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should

we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Ian Broverman.

*** This is a system-generated email notification ***

From: Gerding, Christina * [Christina.Gerding@fda.hhs.gov]
Sent: 12/26/2019 3:36:29 PM
To: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: FW: Corrected Notification: K193547 Acknowledgement Notification
Attachments: K193547 Acknowledgment Letter.pdf

From: Mason, Tiffani * <Tiffani.Mason@fda.hhs.gov>
Sent: Monday, December 23, 2019 10:38 AM
To: mbhenderson@rcri-inc.com
Subject: Corrected Notification: K193547Acknowledgement Notification

Good Morning ,

Resending with corrected trade names,

Thank you ,

Tiffani R. Mason
Tiffani.Mason@fda.hhs.gov
Record Management Specialist 1 DCC 510K

U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

12/23/2019

Mary Beth Henderson, VP Regulatory Affairs and Quality System, System, Senior Principal Advisor
Regulatory and Clinical Research Institute, Inc.
5353 Wayzata Blvd, Suite 505
Minneapolis, MN 55416
UNITED STATES

Dear Mary Beth Henderson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: K193547
Received: 12/20/2019
Applicant: Fin-Ceramica Faenza Spa
Device: CustomizedBone Service

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

January 17, 2020

Fin-Ceramica Faenza Spa
% Mary Beth Henderson, Ph.D., M.B.A.
VP Regulatory Affairs and Quality System, System, Senior Principal Advisor
Regulatory and Clinical Research Institute, Inc.
5353 Wayzata Blvd, Suite 505
Minneapolis, Minnesota 55416

Re: K193547
Trade/Device Name: CustomizedBone Service
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GXN, PJN
Dated: December 19, 2019
Received: December 20, 2019

Dear Mary Beth Henderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Matthew Krueger, M.S.E.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Department of Health & Human Services **Food and Drug Administration**

MEMORANDUM
(K193547)

Date: January 14, 2020

To: Ian Broverman
Team Leader
DNPMD/NDNB

From: Hyung Lee, PhD
Sterility Reviewer
DNPMD/NSDP

Hyung-yul Lee -S 2020.01.14 09:57:32 -05'00'

Device Name: CustomizedBone Service

Sponsor: Fin-Ceramica Faenza S,P.A

(b)(5)

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(b)(5)

(b)(5)

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Special 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the application.

510(k) #: K193547 Date Received by DCC: Dec 20, 2019

Lead Reviewer: Ian Broverman

Center: CDRH Office: OHT 5 Division: DHT5A

Decision:

(•) Accept. If Accept, notify submitter.

( ) Refuse to Accept. If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: ( ) Yes (•) No Click paperclip icon on the left panel if Addendum is attached.

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element.

Special 510(k) Factors

(See "The Special 510(k) Program," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program).

Please complete the below questions to determine if the 510(k) is appropriate for review as a Special 510(k). Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.

	Yes	No
1) 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the manufacturer legally authorized to market the predicate device.	☒	☐
Comments:		
2. Performance data are needed to evaluate the change. *If a manufacturer determines under their design control procedures that no additional verification or validation testing is necessary to evaluate a change, manufacturers may submit these changes as a Special 510(k) with a clear rationale supporting their conclusion that no performance data are necessary. When FDA does not agree with the manufacturer's assessment, FDA intends to continue with the additional Special 510(k) factors.*	☒	☐
Comments:		
3) There is a well-established method to evaluate the change. *Well-established methods include those used in the previously cleared 510(k), an FDA-recognized consensus standard or FDA guidance document, qualified medical device development tools (MDDTs), are widely available and accepted, or found acceptable through a different premarket submission by the same manufacturer of the predicate.*	☒	☐
Comments:		

4) The data can be reviewed in a summary or risk analysis format. *The results from verification and validation associated with design or labeling changes should be able to be placed in a summary or risk analysis format without losing information necessary to support SE. Complete test reports should not be submitted in a Special 510(k). If complete test reports are submitted, FDA intends to assess whether the information can be reviewed in a summary format before converting to a Traditional 510(k).*	☒	☐
Comments:		

Is the submission appropriate for review as a Special 510(k)? *Answer Yes if the change was submitted by the manufacturer of the predicate, well-established methods are available for any performance data necessary, and performance data can be reviewed in a summary or risk analysis format.*

- (●) Yes, submission is appropriate for a Special 510(k). Continue checklist below.
- ( ) No, submission is not appropriate for a Special 510(k). Discontinue this RTA checklist, convert to a Traditional, and apply the Traditional checklist.

Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	☒	☐	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☒	☐	
3) All pages of the submission are numbered.	☒	☐	
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special)	☒	☐	
Comments:			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	☒	☐		☐	
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514], available at https://www.fda.gov/media/72421/download):				☐	
a) Device trade/proprietary name	☒	☐			
b) Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☒	☐			
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements) *See recommended format. (https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*	☒	☐		☐	
4) Submission contains a 510(k) Summary or 510(k) Statement.	☒	☐		☐	
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(l) *See recommended format.* *(https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm)*	☒	☐		☐	
6) Submission is a Class III 510(k) device. *See recommended content (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-class-iii-certification-and-summary).*	☐		☒	☐	
7) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	☒	☐		☐	
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.	☐	☐	☒		
8) The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). *This includes both FDA-recognized and non-recognized consensus standards.*	☒		☐	☐	
a) The submission cites FDA-recognized voluntary consensus standard(s)	☒		☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
i) The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices **OR** If citing general use of a standard as noted in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," the basis of such use is included along with the underlying information or data that supports how the standard was used.	☒	☐			
b) The submission cites non-FDA-recognized voluntary consensus standard(s)	☐		☒		
Combination Product Provisions - Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.			☒		
B. Device Description					
11) The device has a device-specific guidance document, special controls , and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device.	☐		☒	☐	
12) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	☒	☐		☐	
13) The submission includes descriptive information for the device, including the following:				☐	
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	☒	☐			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒	☐			
c) A list and description of each device for which clearance is requested.	☒	☐	☐		
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	☒	☐			
14) A detailed description of all device modification(s) including rationale for each modification. *When labeling or specific technological characteristics (e.g., materials, dimensions) are unchanged in comparison to the predicate, the submission should clearly state that no changes were made.*	☒	☐		☐	
15) Device is intended to be marketed with accessories and/or as part of a system.	☐		☒	☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
C. Substantial Equivalence Discussion					
16) Submitter has identified a predicate device(s), including the following information:				☐	
a) Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710) or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online. (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status)*	☒	☐			
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	☒	☐			
17) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.*				☐	
a) Indications for Use	☒	☐			
b) Technology, including technical specifications, features, materials, and principles of operation	☒	☐			
D. Design Control Activities					
18) Design Control Activities Summary includes all of the following:				☐	
a) Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components **AND** the results of the analysis.	☒	☐			
b) Identification of the device change(s).	☒	☐			
c) Identification of all risks associated with each device change, including identification of risks that are considered new because of the change; and.	☒	☐			
d) Risk control measures to mitigate identified risks (e.g., labeling, verification).	☒	☐			
e) Based on the Risk Analysis, an identification of the verification and/or validation activities required, to comply with 21 CFR 820.30. This identification includes a summary of test methods (including any protocol deviations), acceptance criteria, results in a summary or risk analysis format (e.g., basic descriptive statistics, where appropriate), and why each is adequate to establish substantial equivalence. If unchanged from a previous premarket submission, the manufacturer references the location of protocols and acceptance criteria by providing a submission and section numbers.	☒	☐			

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
i) For non-standardized test methods only: A reference to the protocol used for the existing device with an identification of any differences (e.g., protocol, test conditions, pre-defined acceptance criteria, sample size) from the previous 510(k). If protocol changes were made, the results summary describes why the test methods, acceptance criteria, and results support SE.	☒	☐			
f) A signed statement by the manufacturer's designated individual(s) responsible for design control activities. Both items must be present to answer "Yes." i. Statement that, as required by the risk analysis, all verification and validation activities were performed by designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met. ii. Statement that the submitter has complied and not currently in violation of the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review upon request.	☒	☐			
E. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
19) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	☒	☐		☐	
a) All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified. *FDA recommends clean and redlined copies be provided.*	☒	☐			

Digital Signature Concurrence Table

Reviewer Sign-Off	Ian P. Broverman -S Digitally signed by Ian P. Broverman -S Date: 2020.01.02 19:43:09 -05'00'
Management Sign-Off (digital signature optional)*	

* Management review of checklist and concurrence with with decision required.

Acceptance Checklist for Special 510(k)

In order to facilitate the screening review analysis here below we have responded to any answer of Acceptance Checklist for Special 510(k)s.

Special 510(k) Criteria The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.			
		YES	**NO**
1.	**510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.**	☒	☐
	Comments:		
2.	**Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).**	☒	☐
	Comments:		
3.	**Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).**	☒	☐
	Comments:		
4.	**The submission includes only summary-level information (i.e., NO test reports with performance data).** *Note that if performance data are provided and are conducted under design validation (21 CFR 820.30(g)), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.*	☒	☐
	Comments:		

Does the submission meet all 4 criteria above?

☒ Yes, submission meets criteria for a Special 510(k). Continue checklist below.

☐ No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist, convert to a Traditional and apply the Traditional checklist.

Organizational Elements *Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				
		YES	**NO**	**Page #**
1.	Submission contains Table of Contents.	☒	☐	See TOC
2.	Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.):	☒	☐	
3.	All pages of the submission are numbered.	☒	☐	
4.	Type of 510(k) is identified (traditional, abbreviated, or special)	☒	☐	Cover letter

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during the RTA review.
- • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			**YES**	**NO**	**N/A**	***Page #**
A.	**Administrative**					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			All
		Comments:				
	2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):				
		a. Device trade name or proprietary name	X			Sec. 2
		b. Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			Sec. 2
		Comments:				
	3.	Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") See recommended format (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).	X			4-1
		Comments:				
	4.	Submission contains 510(k) Summary or 510(k) Statement	X			Sec. 5
		Comments:				
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k)	X			Sec. 6
		Comments:				
	6.	Submission is a Class III 510(k) device. *Select "N/A" only if submission is not a Class III 510(k).*			X	Sec. 7
		a. *Class III Summary and Certification*				
		Comments:				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			YES	NO	N/A	*Page #
	7.	The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device. *Prior submissions (or no prior submissions) for this device should be included in Section F (prior related submissions) of the CDRH Premarket Review Submission Cover Sheet form (Form 3514). This information may also be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions).*			X	10-1
		a. If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed. *To address this criterion, it is recommended that the submission include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that adequacy of how the feedback was addressed will be assessed during the substantive review.* *Select "N/A" if the submitter states there were no prior submissions.*			X	
		Comments:				
	Combination Product Provisions – Per 503(g) of the FD&C Act. Select N/A if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison.				X	
	8.	Submission identifies the product as a combination product.			X	
	9.	The combination product contains as a constituent part an approved drug as defined in 21 USC 503(g)(5)(B). Select "N/A" if the combination product does not contain as a constituent part an approved drug. Please also select "N/A" if a right of reference or use for the drug constituent part(s) is included with the submission. If "N/A" is selected, part a below is omitted from the checklist.			X	
		a. The submission includes appropriate patent statement or certification and a statement that the applicant will give notice, as applicable. 21 USC 503(g)(5)(A)&(C).			X	
		Comments:				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			YES	NO	N/A	*Page #
B.	**Device Description**					
	10.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device. *If "N/A"is selected, parts a and b below are omitted from the checklist.*		X		
		a) The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.			X	
		b) The submission includes device description information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*			X	
		Comments:				
	11.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling). ***Comments:* Please refer to section 11 device description**	X			Sec.11 and Sec. 13
		Comments:				
	12.	The submission includes descriptive information for the device, including the following:	X			Sec. 11
		a) A description of the principle of operation or mechanism of action for achieving the intended effect.	X			
		b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
		c) A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc.*			X	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			YES	NO	N/A	*Page #
		d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	X			
		Comments:				
	13.	A description of all device modification(s) including rationale for each modification.	X			Sec. 10.4
		Comments:				
	14.	Device is intended to be marketed with multiple components, accessories, and/or as part of a system. *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system. If "N/A" is selected, parts a-c below are omitted from the checklist.*			X	
		a) Submission includes a list of all components and accessories to be marketed with the subject device.			X	
		b) Submission includes a description (as detailed in item 12a., 12b., and 12d. above) of each component or accessory. *Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*			X	
		c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance AND A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.			X	
		Comments: **The proposed device is not intended to be marketed with multiple components**				
C.	**Substantial Equivalence Discussion**					
	15.	Submitter has identified a predicate device(s), including the following information:				
		a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status.	X			Sec. 12

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			YES	NO	N/A	*Page #
		Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm.*				
		b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	X			Sec. 12
		Comments:				
	16.	Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR807.87(f)]	X			Sec, 12
		a) Indications for Use *If there are no differences between the subject device and the predicate(s) with respect to indications and intended use, this should be explicitly stated.*	X			Sec. 12.3
		b) Technology, including features, materials, and principles of operation. *Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation.* *FDA recommends a tabular format for comparing technological characteristics. Any characteristic that is the same as the predicate(s) should be explicitly stated. Differences in technological characteristics should be identified and a rationale provided why they do not raise different questions of safety and effectiveness.*	X			Sec. 12
		Comments:				
D.	**Design Control Activities**					
	17.	Design Control Activities Summary includes all of the following:	X			Sec. 10.3
		a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components AND the results of the analysis	X			Sec. 10.3
		b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria.	X			Sec. 10.3

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			YES	NO	N/A	*Page #
		c) Declaration of conformity with design controls. All 3 below must be present to answer "yes". i. Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met. ii. Statement that manufacturing facility is in conformance with design control with design control procedure requirements as specified in 21CFR 820.30 iii. Statement is signed by the individual responsible for these activities.	X			Sec. 9.1
		Comments:				
E.	**Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)**					
	18.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	X			Sec. 13
		a). All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.	X			Annex 13-1
		Comment				
	19.	Statement that the intended use of the modified devices, as described in the labeling , has not changed as a result of the modification (s)	X			Sec. 12.3
		Comments:				

From: Mason, Tiffani * [Tiffani.Mason@fda.hhs.gov]
Sent: 12/20/2019 9:23:44 PM
To: mbhenderson@rcri-inc.com
Subject: Corrected Notification: K193547 Acknowledgement Notification
Attachments: K193547 Acknowledgment Letter.pdf

Good Afternoon,

Resending with corrected Subject line,

Thank you ,

Tiffani R. Mason

Tiffani.Mason@fda.hhs.gov

Record Management Specialist 1 DCC

510K

U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

12/20/2019

Mary Beth Henderson, VP Regulatory Affairs and Quality System, System, Senior Principal Advisor
Regulatory and Clinical Research Institute, Inc.
5353 Wayzata Blvd, Suite 505
Minneapolis, MN 55416
UNITED STATES

Dear Mary Beth Henderson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: K193547
Received: 12/20/2019
Applicant: Fin-Ceramica Faenza Spa
Device: CustomizedBone Service

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

Hi Hyung,

FinCeramica sent a 4-page response. Please let me know what you think.

-Ian

From: Henderson, Mary Beth <MaryBeth.Henderson@covance.com>

Sent: Wednesday, January 15, 2020 12:12 PM

To: Broverman, Ian <Ian.Broverman@fda.hhs.gov>

Cc: Marina Monticelli <mmonticelli@finceramica.it>

Subject: RE: K193547

Ian-

Please see attached FinCeramica's response to your questions below. Please don't hesitate to e-mail or call, if you have any additional questions.

Best-

Mary Beth

Mary Beth Henderson, Ph.D., MBA

Executive Director, Covance Medical Device and Diagnostic Solutions

Covance Inc

5353 Wayzata Blvd. Suite 505

Minneapolis, MN 55416

Direct: +1-952-595-5580 Main: +1-952-746-8080 Cell: (b)(6)

marybeth.henderson@covance.com<mailto:marybeth.henderson@covance.com>

[cid:image002.jpg@01D5C21D.483E24D0]

Please note my email address has changed. As of 01 January 2020, RCRI is part of Covance, Medical Device and Diagnostic Solutions. Emails sent to my RCRI email address after January 1st will automatically be forwarded to my Covance email. However, emails from me will be sent from my Covance email address.

From: Broverman, Ian <Ian.Broverman@fda.hhs.gov<mailto:Ian.Broverman@fda.hhs.gov>>

Sent: Tuesday, January 14, 2020 12:00 PM

To: Mary Beth Henderson <mbhenderson@rcri-inc.com<mailto:mbhenderson@rcri-inc.com>>

Subject: [External] K193547

Importance: High

EXTERNAL: This email originated from outside of the organization. Do not click any links or open any attachments unless you trust the sender and know the content is safe.

K193547

Hi Mary Beth,

Below are two requests for additional information from our (b)(4). If you can respond to them by tomorrow morning, we will do our best to complete the review by Friday.

If the response is not available by then, we would have to place the file on Hold to give reviewers enough time to go over new information and prepare final documents. Please let me know if tomorrow morning is feasible for your response.

(b)(4)

Thank you,

-Ian

Ian Broverman

Medical Device Reviewer

Neurosurgical Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices

OHT5: Office of Neurology and Physical Medicine Devices

Center for Devices and Radiological Health

Office of Product Evaluation and Quality

U.S. Food and Drug Administration

Tel: 301-796-9696

ian.broverman@fda.hhs.gov<mailto:ian.broverman@fda.hhs.gov>

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Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1711&S=E<https://nam04.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.proofpoint.com%2Fv2%2Furl%3Fu%3Dhttps-

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S3Tci6FGhdwJDQDA8NxOis%3D&reserved=0>

Hi Mary Beth,

(b)(4)

Sorry to make you go through this drill again. We are finishing up the other parts of the review as quickly as possible in hopes of making the Friday target.

Thank you,

-Ian

From: Lee, Hyung <Hyung-Yul.Lee@fda.hhs.gov>
Sent: Wednesday, January 15, 2020 2:53 PM
To: Broverman, Ian <Ian.Broverman@fda.hhs.gov>
Subject: RE: K193547

Hi Ian,

Here is the following request I have for the sponsor's response to the interactive review request #1. Please let me know if you have any questions. Thank you.

Hyung

(b)(4)

From: Broverman, Ian <Ian.Broverman@fda.hhs.gov>
Sent: Wednesday, January 15, 2020 1:25 PM
To: Lee, Hyung <Hyung-Yul.Lee@fda.hhs.gov>
Subject: FW: K193547
Importance: High

Hi Hyung,

FinCeramica sent a 4-page response. Please let me know what you think.

-Ian

From: Henderson, Mary Beth <MaryBeth.Henderson@covance.com>
Sent: Wednesday, January 15, 2020 12:12 PM
To: Broverman, Ian <Ian.Broverman@fda.hhs.gov>
Cc: Marina Monticelli <mmonticelli@finceramica.it>
Subject: RE: K193547

Ian—
Please see attached FinCeramica's response to your questions below. Please don't hesitate to e-mail or call, if you have any additional questions.
Best—
Mary Beth

Mary Beth Henderson, Ph.D., MBA
Executive Director, Covance Medical Device and Diagnostic Solutions
Covance Inc
5353 Wayzata Blvd. Suite 505
Minneapolis, MN 55416
Direct: +1-952-595-5580 Main: +1-952-746-8080 Cell: (b)(6)
marybeth.henderson@covance.com

cid:image002.jpg@01

Please note my email address has changed. As of 01 January 2020, RCRI is part of Covance, Medical Device and Diagnostic Solutions. Emails sent to my RCRI email address after January 1st will automatically be forwarded to my Covance email. However, emails from me will be sent from my Covance email address.

From: Broverman, Ian <Ian.Broverman@fda.hhs.gov>
Sent: Tuesday, January 14, 2020 12:00 PM
To: Mary Beth Henderson <mbhenderson@rcri-inc.com>
Subject: [External] K193547
Importance: High

EXTERNAL: This email originated from outside of the organization. Do not click any links or open any attachments unless you trust the sender and know the content is safe.

K193547

Hi Mary Beth,

Below are two requests for additional information from ou (b)(4) If you can respond to them by tomorrow morning, we will do our best to complete the review by Friday.
If the response is not available by then, we would have to place the file on Hold to give reviewers enough time to go over new information and prepare final documents. Please let me know if tomorrow morning is feasible for your response.

(b)(4)

Thank you,

-Ian
Ian Broverman
Medical Device Reviewer
Neurosurgical Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurology and Physical Medicine Devices

Center for Devices and Radiological Health
Office of Product Evaluation and Quality
U.S. Food and Drug Administration
Tel: 301-796-9696
ian.broverman@fda.hhs.gov

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Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1711&S=E

Dear Ms. Henderson,

Happy new year. I am leading the review of K193547, and look forward to working with you. To expedite the process, I have a couple of requests:

Please email me a clean copy of the Indications for Use form 3881, without the headers & footers from the submission. You may add the 510(k) number K193547 to the form, or I can add it when we complete the file.

(b)(4)

Thank you very much,

-Ian
Ian Broverman
Medical Device Reviewer
Neurosurgical Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurology and Physical Medicine Devices

Center for Devices and Radiological Health
Office of Product Evaluation and Quality
U.S. Food and Drug Administration
Tel: 301-796-9696
ian.broverman@fda.hhs.gov


cid:image002.png@01D50106.C
9360590

From: Ian Broverman <ian.broverman@fda.hhs.gov>
Sent: Friday, January 3, 2020 11:34 AM
To: mbhenderson@rcri-inc.com
Cc: Broverman, Ian <Ian.Broverman@fda.hhs.gov>
Subject: K193547 was Accepted

January 3, 2020

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K193547, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Ian Broverman.

*** This is a system-generated email notification ***

U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/ODE/DNPMD/NDNB
WO66 RM4202
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-9696

Premarket Notification 510(k) Review

Date: January 16, 2020

Reviewer: Ian Broverman

Subject: Special 510(k)# K193547

Applicant: Fin-Ceramica Faenza Spa	**Device Trade Name:** CustomizedBone Service
Contact Name: Mary Henderson	**Contact Title:** VP Regulatory Affairs and Quality System, System, Senior Principal Advisor
Correspondent Firm: Regulatory and Clinical Research Institute, Inc.	**Phone:** (952) 595-5580 **Email:** mbhenderson@rcri-inc.com
Received Date: December 20, 2019	**Due Date:** January 19, 2020
Pro Code(s): GXN **Class:** II **Reg #:** 882.5330	**Reg Name:** Preformed Nonalterable Cranioplasty Plate
Pro Code(s): PJN Class: II Reg #: 882.5330	Reg Name: Preformed nonalterable cranioplasty plate

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K180513	GXN, PJN	CustomizedBone Service	Fin-Ceramica Faenza S.p.A

(b)(5)

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(b)(5)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193547

Device Name
CustomizedBone Service

Indications for Use *(Describe)*
CustomizedBone Service (CustomizedBone) is intended to replace bony voids in the cranial and /or craniofacial skeleton (frontal bone including the brow ridge). This device is indicated for both adult and pediatric use (for children 7 years of age and above).
CustomizedBone implants are suitable for reconstructing cranial and/or craniofacial defects resulting from:
• trauma and vascular pathologies, either associated or non-associated to cranial decompression:
• removal of tumours:
• reabsorption of autologous bone:
• rejection of other prosthetic materials:
• congenital malformations.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

CUSTOMIZEDBONE SERVICE

PATIENT SPECIFIC CRANIAL/CRANIOFACIAL IMPLANT

INSTRUCTIONS for USE

CAUTION:
FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

DESCRIPTION

Hydroxyapatite is contained in human bones in percentage close to 70% and is one of the most important elements of human bone structure. CustomizedBone Service patient specific implants for the reconstruction of cranial/craniofacial defects are made of porous bio-mimetic hydroxyapatite with a chemical composition and structure that resembles the mineral component of human bones. This biomaterial is highly porous with trabecular structure and is composed of pores with the following characteristics:

- ✓ macro-pores,
- ✓ interconnecting pores,
- ✓ micro-pores.

This material is completely biocompatible.
The implants are designed and produced by Fin-Ceramica Faenza according to the surgeon's specifications and based on the patient's CT scan data, obtained through a standardized protocol. During the pre-operative planning phase, the surgeon must approve the final implant design. All the implants are accompanied by the patient's identification code.

INDICATIONS FOR USE

CustomizedBone Service (CustomizedBone) is intended to replace bony voids in the cranial and/or craniofacial skeleton (frontal bone including the brow ridge) . This device is indicated for both adult and pediatric use (for children 7 years of age and above).
CustomizedBone implants are suitable for reconstructing cranial and/or craniofacial defects resulting from:

- ✓ trauma and vascular pathologies, either associated or non-associated to cranial decompression;
- ✓ removal of tumours;
- ✓ reabsorption of autologous bone;
- ✓ rejection of other prosthetic materials;
- ✓ congenital malformations.

AVAILABLE FORMATS

CustomizedBone implants are patient specific; the devices are designed based upon the prescription of a qualified surgeon and based upon patient CT scan data. Each patient-specific implant is supplied with an equivalent secondary back-up device. The implants are supplied sterile. The CustomizedBone Service Implants are MR safe.

INSTRUCTIONS for USE

These instructions are intended as guidelines for the use of CustomizedBone implants; they are not designed to replace or change the standard procedures for the treatment of cranial defects.
Clinical results of implants used for the reconstruction of cranial defects depend on several factors. When choosing an implant and the surgical technique to be used, the following factors need to be considered: patient's age and general clinical conditions, and bone quality. Moreover, the possibility of achieving good contact between the implant and the vital host bone, complete defect filling and correct and sufficient primary stabilization of the implant need to be evaluated.
Prior to the surgical intervention, ensure that the implant identification data match those of the patient as detailed in the patient's documents and medical records. In addition, all documents related to the implant have to be carefully checked so as to make sure that the implant is an exact match to the bone gap which is to be treated.

Pre-operative treatment
As per surgical practice prior to the surgery, the patient should be administered standard antibiotic treatment. In patients that are allergic to specific antibiotic, an alternative treatment should be considered. It is necessary to carefully verify that no infection or inflammation is present at the surgical site.

Intra-operative aspects
Once the cranial defect has been exposed, it is necessary to remove any fibrotic or dural tissues from the host bone edges to ensure maximum surface contact between the vital host bone and the implant. CustomizedBone healing is highly favored when the implant is in contact with the greatest amount of vital bone tissue. Avoid exerting excessive pressure on the implant while positioning it; incorrect handling could lead to implant damage. Prepare the suture holes on the edges of the bone to align with those on the edges of the prosthesis. Then secure the implant using suture thread with a diameter less than 2 mm. Do not use absorbable sutures or any screws for implant fixation. Prepare holes along the edge at a distance of 0.5-1.0 cm from the defect area to align with the suture holes on the edges of the prosthesis.
Some holes could also be present in the central part of the implant to allow for dural suspension; the decision to perform a dura suspension is left to the surgeon's discretion. Once the implant fixation is completed, the surgical site should be closed according to standard procedures.

Post-operative procedure
In accordance with standard post-surgical procedures, a peri-operative antibiotic therapy should be administered.
The surgeon must provide the patient with all the indications for a correct post-operative recovery in relation to the localisation and entity of the defect as well as the overall clinical picture. The patient should be advised to avoid direct traumas to the implant area.

CONTRAINDICATIONS

Use of a CustomizedBone implant is contraindicated in the presence of inflammatory conditions and/or infection of the surgical area to be treated; in insufficiently vascularized sites; if dura mater wounds/lacerations are present; and in areas in which the patient's skin tissue is not sufficient to cover the implant entirely.

In addition, CustomizedBone Service is contraindicated for used in the following patient categories:

- patients suffering from a proven hypersensitivity to calcium phosphates
- patients affected by bone demineralization diseases,
- patients with chronic brain hypertension or coagulation disorders,
- patients with an ongoing bacterial or viral infection(s),
- patients on steroid therapy

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WARNINGS and PRECAUTIONS

- The use of CustomizedBone implant is reserved exclusively to qualified medical specialists.
- In pre- and intra-operative phases the device must be handled with the greatest care, avoiding any manoeuvres that might damage or contaminate the device.
- Hydroxyapatite-based cranioplasty devices have been shown in pre-clinical and clinical studies to potentially result in implant fractures in <2% of cases. The fracture rates and explantation rates are higher in children and shown below in the adverse effects section.
- The device is patient-specific and manufactured exclusively for the patient indicated on the physician's prescription. Thus do not modify the patient-specific device in any way. Any modification to the supplied device shall be the sole and exclusive responsibility of the surgeon. IIf during surgery a modification of the implant is deemed necessary by the surgeon, however, it should be made with extreme caution, only by using low speed diamond drills under water irrigation.
- In order to help achieve adequate device fixation, surgeons are recommended to carefully evaluate the device, both during design validation and during surgery including any condition leading to elevated intracranial pressure or brain herniation which may hinder proper implant positioning
- In cases of frontal sinus reconstruction, to prevent any possible risk of post-op bacterial contamination, it is necessary to assure the implant is not directly exposed to the open nasal tracts/airways.
- The implant should be fixed to the host bone by non-absorbable suture (diameter smaller than 2 mm). Do not use absorbable sutures or metallic screws for implant fixation.
- A skin expander or similar techniques to generate additional skin,should no be used concurrently with implantation of the CustomizedBone device.
- The indications and warnings given to the patient by the surgeon for the post-operative period are extremely important; in particular, patients should be warned to avoid direct traumas in the implant area. Violent blows to the implant area might lead to complications such as implant mobilisation and/or fracture. During the first post-operative year any stress on the implanted area should be avoided. CustomizedBone implants are single-use products; any unused devices or post-operative device residue must be disposed off as per local regulations. The product may not be re-sterilised.
- The product should not be used if the internal packaging has been opened or damaged. Do not use the product if it has expired.
- Prior to surgery, it is imperative to check the labels on the implant and to make sure all the patient's labels are present and matching the traceability information on the implant and on all the packaging parts. The package contains additional labels with the product's traceability details.
- If, during the surgery, the device is accidentally damaged or contaminated, surgery should be completed using the back-up implant. The back-up implant could be used also in case of re-operation but only under surgeon discretion after evaluation of the congruence between the new cranial void and the device.
- No specific, product-related adverse events have been reported when CustomizedBone implants have been used in oncological patients. Nonetheless, patients implanted with a CustomizedBone implant following brain tumour removal should be carefully monitored post-surgically.
- According to available post-marketing surveillance data, there may be a greater chance of adverse events and/or device explantation in pediatric patients 7-12 years of age as compared to pediatric patients older than 13 years of age.
- The safety and effectiveness of CustomizedBone Service has not been evaluated for defect sizes greater than 250 cm^2.

ADVERSE EFFECTS

Procedure Related:
As with all surgical procedures and as for craniotomy and cranioplasty, complications may be expected. These complications include, but are not limited to: headache, nausea, device contamination during surgery, surgical site infection or dehiscence, scar tissue formation, incisional discomfort or pain, intracranial hemorrhage, hydrocephalus, fever, pain, inflammation, seizures, brain swelling, implant malposition, nerve damage, paresthesia, cerebrospinal fluid leak, deep vein thrombosis, neurological injury and/or death.

Device Related:
Complications and adverse events can occur when using any synthetic, customized cranioplasty device. For CustomizedBone implants, complications could include, but are not limited to:

- Implant infection;
- implant mobilization;
- implant fracture.

Some minor adverse events could be conservatively treated, while severe conditions could require reoperation or implant removal.

The tables below provide information on the expected device use outcomes by summarizing adverse events observed in pediatric and adult patients (Table 1) and as relate to device size (Table 2):

Table 1

Patient Age	Adverse Events (Rate)	Fractures (Rate)	Infection (Rate)	Mobilization (Rate)	Explantations (Rate)
Children 7 – 12 years	19 (9.5%)	9 (4.5%)	4 (2.0%)	3 (1.5%)	11 (5.5%)
Children 13 – 21 years	35 (5.7%)	19 (3.1%)	13 (2.1%)	1 (0.2%)	24 (3.9%)
Adults >21 years	156 (3.8%)	34 (0.8%)	80 (1.9%)	13 (0.3%)	111 (2.7%)

Rates based on 812 pediatric and 4,087 adults cases

Table 2

Device Size	Number of cases	Adverse Events (Rate)	Fractures (Rate)	Infection (Rate)	Mobilization (Rate)	Explantations (Rate)
≤100 cm^2	605	14 (2.3%)	3 (0.5%)	7 (1.2%)	3 (0.5%)	8 (1.3%)
101 – 150 cm^2	703	21 (3.0%)	5 (0.7%)	9 (1.3%)	1 (0.1%)	14 (2.0%)
151 – 200 cm^2	257	9 (3.5%)	3 (1.2%)	4 (1.6%)	0 (0.0%)	6 (2.3%)
201 – 250 cm^2	37	3 (8.1%)	1 (2.7%)	2 (5.4%)	0 (0.0%)	2 (5.4%)
Total	1602	47 (2.9%)	12 (0.8%)	22 (1.4%)	4 (0.3%)	30 (1.9%)

Rates based on 1,602 devices

STERILIZATION

All CustomizedBone products are supplied sterile (i.e sterilized with gamma rays 25 kGy or steam). The products are single-use and may not be re-sterilised. This product is intended for single use and must not be re-sterilized. Its reuse, in whole or in part, may involve the risk of cross contamination and the danger of infection at the implant site.

STORAGE

The product must be stored in a cool, dry area, and should be protected from direct light and heat sources (+ 10° C /+ 40°C)

SYMBOLS GLOSSARY

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	ISO 15223-1, Clause 5.1.1	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1, Clause 5.1.5	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1, Clause 5.7.1	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements	Patient number	Indicates a unique number associated with an individual patient.
	ISO 15223-1, Clause 5.1.6	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1, Clause 5.2.6	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements	Do not resterilize	Indicates a medical device that is not to be resterilized.
	ISO 15223-1, Clause 5.4.2	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 15223-1, Clause 5.2.8	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 15223-1, Clause 5.4.3	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements	Consult instruction for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1, Clause 5.4.4	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	ISO 15223-1, Clause 5.2.4	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.
	ISO 15223-1, Clause 5.2.5	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements	Sterilized using steam or dry heat	Indicates a medical device that has been sterilized using steam or dry heat.
	ISO 15223-1, Clause 5.3.2	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements	Keep away from sunlight	Indicates a medical device that needs protection from light sources
	ISO 15223-1, Clause 5.1.4	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements	Use-by date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1, Clause 5.3.4	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements	Keep dry	Indicates a medical device that needs to be protected from moisture.
	ISO 15223-1, Clause 5.3.7	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223-1, Clause 5.3.1	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements	Fragile; handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
	ISO 7000 - 0623	Graphical symbols for use on equipment – Registered Symbols	This way up	Indicates correct upright position of the transport package.
	ASTM F2503	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	MR Safe	Safe for use in magnetic resonance imaging.
	N/A	N/A	Pieces number	The number of pieces within the package.
	21 CFR 801.15(c)(1)(i)(F)	Labeling - Medical devices; prominence of required label statements; use of symbols in labeling.	Prescription use only	Requires prescription in the United States.
	21 CFR 801.109(b)(1)	Labeling - Prescription devices.		

Manufacturer:

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48018 Faenza (RA) - ITALY
Administrative offices: Via Granarolo, 177/3
Manufacturing site: Via Ravegnana, 186
Tel. +39 0546 607311
Email: info@finceramica.it

CustomizedBone Service

Packaging Handling Instructions

This product has been sterilized by Steam Process.
Carefully follow the instructions for opening the packaging.

CustomizedBone Service

Packaging Handling Instructions

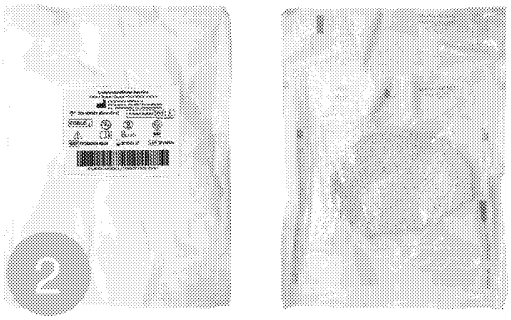
NON STERILE

1
NON Sterile Wrap

Open the first pouch out of the sterile field.

NON STERILE

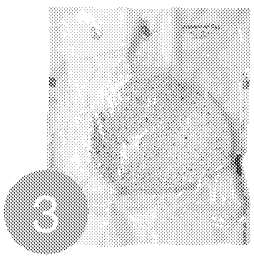
2
NON Sterile Wrap



Open the second pouch, making sure that the third inner pouch is open in the sterile field.

STERILE

3
STERILE Wrap



Attention! Third pouch is sterile, be careful not to contaminate.

Finceramica regenerative surgery

INTEGRA

Codman Specialty Surgical

MDJ000500-23-00

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193547

Device Name
CustomizedBone Service

Indications for Use *(Describe)*
CustomizedBone Service (CustomizedBone) is intended to replace bony voids in the cranial and /or craniofacial skeleton (frontal bone including the brow ridge). This device is indicated for both adult and pediatric use (for children 7 years of age and above).
CustomizedBone implants are suitable for reconstructing cranial and/or craniofacial defects resulting from:
• trauma and vascular pathologies, either associated or non-associated to cranial decompression:
• removal of tumours:
• reabsorption of autologous bone:
• rejection of other prosthetic materials:
• congenital malformations.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K193547

Hi Mary Beth,

Below are two requests for additional information from our (b)(4) If you can respond to them by tomorrow morning, we will do our best to complete the review by Friday.
If the response is not available by then, we would have to place the file on Hold to give reviewers enough time to go over new information and prepare final documents. Please let me know if tomorrow morning is feasible for your response.

(b)(4)

Thank you,

-Ian
Ian Broverman
Medical Device Reviewer
Neurosurgical Devices Team
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurology and Physical Medicine Devices

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